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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,624	01/26/2000	Carlos Picornell Darder	4948-2P/C/RCE	8816

7590 06/01/2004

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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/491,624	DARDER, CARLOS PICORNELL	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13 and 15-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Request for Continued Examination received on March 15, 2004 is acknowledged. Claims 1-13 and 15-40 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-13, 26-29, and 37-38 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,132,771 to Depui et al.

Depui et al disclose an oral pharmaceutical dosage form comprising a proton pump inhibitor (abstract). More specifically, Depui et al disclose that the proton pump inhibitor can be selected from omeprazole, lansoprazole, pantoprazole, pariprazole, and leminoprazole. See column 4 to 6. Additionally, Depui discloses that the core material for their composition is a seed layered with the proton pump inhibitor along with an

enteric coating. See column 8, lines 48-50. Depui et al. also teach that the seeds can be made of different materials, including sugars. See column 8, line 58. The reference discloses mixing the proton pump inhibitor with other components prior to layering on the seeds, wherein the components can include binders, surfactants, disintegrating agents, and fillers. See column 9, lines 1-5. The binder can be selected from HPM, HPMC, CMC, PVP, sugars and starches. See column 9, lines 3-6. The alkaline substance can be selected from sodium potassium, calcium, magnesium, and aluminum salts of phosphoric acid, carbonic acid, citric acid, and other weak acids, as well as magnesium oxide substances, and other substances normally used in antacid compositions. See column 9, lines 27-42. The surfactant disclosed is sodium lauryl sulfate. See column 9, lines 10. Lactose monohydrate and mannitol are utilized in the examples. Depui et al disclose that the seeds have a size between 0. 1 and 2 mm, which equals 100 to 2000 micrometers. See column 8, line 62. Most importantly, Depui et al state that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Depui et al disclose a middle, separating layer is optional, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. The enteric coating layer is selected from I-IPMCP, methacrylic acid polymers, HPMC acetate succinate, and shellac. See column 10, lines 46-53. Further, the enteric coating layer includes a plasticizer: PEG or cetyl alcohol, anti-tacking agents, and pigments. See column 10, lines 58-60 and column 11, lines 1-10.

Claims 15-25, 30-34, 36, and 39-40 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,365,184 to Depui et al.

Depui et al disclose an oral pharmaceutical dosage form comprising a proton pump inhibitor and an NSAID (abstract). More specifically, Depui et al disclose that the proton pump inhibitor can be selected from omeprazole, lansoprazole, pantoprazole, pariprazole, and leminoprazole. See column 4 to 6. Additionally, Depui discloses that the core material for their composition is a seed layered with the proton pump inhibitor along with an enteric coating. See column 8, lines 48-50. Depui et al. also teach that the seeds can be made of different materials, including sugars. See column 8, line 58. The reference discloses mixing the proton pump inhibitor with other components prior to layering on the seeds, wherein the components can include binders, surfactants, disintegrating agents, and fillers. See column 9, lines 1-5. The binder can be selected from HPM, HPMC, CMC, PVP, sugars and starches. See column 9, lines 3-6. The alkaline substance can be selected from sodium potassium, calcium, magnesium, and aluminum salts of phosphoric acid, carbonic acid, citric acid, and other weak acids, as well as magnesium oxide substances, and other substances normally used in antacid compositions. See column 9, lines 27-42. The surfactant disclosed is sodium lauryl sulfate. See column 9, lines 10. Lactose monohydrate and mannitol are utilized in the examples. Depui et al disclose that the seeds have a size between 0. 1 and 2 mm, which equals 100 to 2000 micrometers. See column 8, line 62. Most importantly, Depui et al state that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Depui et al disclose a middle, separating layer

is optional, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. The enteric coating layer is selected from I-IPMCP, methacrylic acid polymers, HPMC acetate succinate, and shellac. See column 10, lines 46-53. Further, the enteric coating layer includes a plasticizer: PEG or cetyl alcohol, anti-tacking agents, and pigments. See column 10, lines 58-60 and column 11, lines 1-10. The examples utilize a Wurster-type fluidized apparatus to coat the active agent onto the sugar core, followed by an enteric coating. See example 4.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-13 and 15-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,132,771 to Depui et al.

The teaching of Depui et al are set forth in detail above. Depui et al state that their formulation does not necessarily include a spacing layer between the coated seed

and an enteric coating. Thus, Depui et al provides two embodiments, one for a optional separating layer and the second embodiment wherein the formulation implicitly does not contain a separating layer. Depui et al disclose a middle, separating layer is ***optional***, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. Depui et al disclose the use of a fluid bed apparatus for coating. See examples. Depui states in the section titled "Background of the Invention" that it is known to formulate dosage forms containing only proton pump inhibitors or prokinetic agents respectively. Column 2, lines 25-31, the reference states that "combination therapy is considered for patients whose predominant symptom is regurgitation...those with respiratory problems...those with cough and hoarseness related to reflux disease."

In regard to the composition claims 1-13, 26-29, and 37-8, assuming one were to argue that Depui et al do not clearly anticipate the claims since Depui et al do not explicitly state that there is no separating layer, it is deemed obvious to one of ordinary skill in the art at the time the invention was made to make Depui et al's formulation with an inert core, ac active coating, and an enteric coating, excluding a the separating layer. One would be motivated to do so since with a reasonable expectation of success since Depui clearly states that the separating layer is optional and thus the usage of the term "optional" is implicit that the formulation can functional stably without such a layer without a detrimental affect. Therefore, the removal of the separating layer is prima facie obvious to a skilled artisan.

In regards to claim 35 limiting the formulation to one active, the reference does specifying the use of only one active. However, it is deemed obvious of ordinary skill in the art at the time the invention was made to look to the guidance of Depui et al and only utilize one active agent. One would be motivated to do so since Depui et al clearly states that utilizing only proton pump inhibitors or prokinetic agents respectively is known and conventional and that combination therapy is utilized for patients with respiratory problems, reflux disease, etc. Therefore, it prima facie obvious to a skilled artisan that if a patient did not experience the symptoms as discussed by Depui, one would utilize a single active and Depui's alternative embodiment of combination therapy.

In regards to the process claims 15-25, 31-34, and 36, although Depui et al disclose the use of a fluid bed apparatus for the coating process, the reference does not state specify the type of fluid bed apparatus, i.e. Wurster-type fluidized bed apparatus. However, this is deemed obvious to one of ordinary skill in the art at the time the invention was made to utilize the appropriate type of fluid bed apparatus since these parameters are readily apparent to those skilled in the art and the criticality lies in the formulation of the composition and the process of coating onto the core. Thus, it is the examiner's position absent unexpected data, that the type of the apparatus used, i.e. Wurster-type fluidized apparatus versus a fluidized apparatus, does not impart a patentable difference since the prior art's apparatus provides the same function, i.e. the coating of layers onto the seed.

Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,132,771 to Depui et al in view of Lovgren et al (4,853,230).

The teaching of Depui et al are set forth in detail above. Depui states in the section titled "Background of the Invention" that it is known to formulate dosage forms containing only proton pump inhibitors or prokinetic agents respectively. Column 2, lines 25-31, the reference states that "combination therapy is considered for patients whose predominant symptom is regurgitation...those with respiratory problems...those with cough and hoarseness related to reflux disease."

The reference does specifying the use of only one active.

Lovegren teaches a pharmaceutical formulation of an acid labile substance for oral use. See abstract. The instant drugs are taught. See Table 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to look to the guidance of Lovgren et al and create a formulation with only a single active ingredient of a proton pump inhibitor. One would be motivated to do so since Lovegren is relied upon to demonstrate the state of the art that it is known in the art to create formulations comprising a proton pump inhibitor as the single active. One would be motivated to do so if one desired only single active therapy for treating the desired symptoms compared to combination therapy as taught by Depui. Therefore, this invention as a whole would have been prima facie obvious to one of ordinary skill in art at the time the invention was made.

Claims 15-25, 31-34, 36, and 39-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,132,771 to Depui et al in view of Ohno et al (4,017,647) or Wurster (2,799,241).

The teaching of Depui et al are set forth in detail above. Depui et al disclose the use of a fluid bed apparatus for coating.

Depui et al do not specify the type of fluidized bed apparatus utilized.

Ohno et al teach a method for providing an enteric coating on solid dosage forms. The enteric coating solution contains those taught in Depui et al, i.e. film-forming polymers (HPMC), plasticizers, pigments, etc. on column 2. Ohno et al teach the use of a conventional coating machine such as pan coaters, drum-type coaters, or Wurster-type fluidizing caters, and Glatt fluidizing coater since there is no principle difference between coating solid dosage forms and all conventional coaters work under the same principle of utilizing a coating solution. See column 3, lines 24-40.

Wurster teaches the Wurster-type fluidized apparatus provides for a uniformed coating an preventing the coating material from sticking to the inner surface of the chamber. See column 1, lines 22-35.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teaching of Depui et al and Ohno et al and utilize the fluidized apparatus of choice such as instant Wurster-type. One would be motivated to do so since Ohno teaches that the Wurster-type apparatus among other fluid bed coaters are known and conventionally utilized in the art for coating purposes and all the coating machines work under the same principle. Therefore, it is prima facie obvious to utilize the instant Wurster-Type in Depui's process with a reasonable expectation of success since not only does Depui teach the use of a fluid bed apparatus but Ohno teaches the equivalency of all coating machines.

Further, it would have been obvious to look at Wurster and utilize the instant apparatus. One would be motivated to do so since Wurster teaches that the Wurster-type provides a uniform coating. Further, the Wurster patent demonstrates that the Wurster-Type apparatus is not a new type of apparatus and as been known in the art since the 1940s. Therefore, it is reasonable for a skilled artisan to utilize a conventional machine routinely utilized in the pharmaceutical coating art, this does not impart patentability.

Claims 1-13, 26-29, and 37-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,365,184 to Depui et al.

The teaching of Depui et al are set forth in detail above. Depui teaches the use of the NSAID for its anti-inflammatory effects and the instant active for its gastric acid inhibition. Depui et al state that their formulation does not necessarily include a spacing layer between the coated seed and an enteric coating. Thus, Depui et al provides two embodiments, one for a optional separating layer and the second embodiment wherein the formulation implicitly does not contain a separating layer. Depui et al disclose a middle, separating layer is ***optional***, and the enteric coating can be applied directly to the coated core. See column 9, lines 46-50 and column 10, lines 41-43. Depui states in the section titled "Background of the Invention" that it is known to formulate dosage forms containing only proton pump inhibitors or prokinetic agents respectively. Column 2, lines 25-31, the reference states that "combination therapy is considered for patients whose predominant symptom is regurgitation...those with respiratory problems...those with cough and hoarseness related to reflux disease."

Depui et al does not specify the use of a single active agent, i.e. the anti-ulcer drug.

It is deemed obvious to one of ordinary skill in the art at the time the invention was made to utilize Depui's anti-ulcer drug without the NSAID. One would be motivated to omit an element and its function, it the element is not desired. Thus, in instant case it is obvious to exclude Depui's NSAID if one did not desire to treat pain or inflammation and only wished to treat gastric disorder.

Response to Arguments

Applicant argues that although US patent 6,132,771, hereafter referred to as Depui et al, recognizes the need for an enteric coating to protect the proton pump inhibitor from the acidic gastric juices, Depui main objective does not provide for an enteric coating of the proton pump inhibitor.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner is unclear as to what exactly is being argued by the applicant since the applicant clearly states that Depui et al recognizes the need for an enteric coat to protect the acid susceptible proton inhibitor. It is quite clear that Depui et al disclose the use of an enteric coat as clearly seen on column 3, lines 18-23 wherein Depui states that Figure 1 is a cross-section of a dosage form comprising an acid susceptible proton pump inhibitor *in the form of an enteric coating layered pellet.*

Applicant argues that Depui et al fail to describe a stable and useful oral form of a proton pump inhibitor without an alkaline substance and at least one separating layer.

It is argued that Depui fails to enable such a dosage form. Applicant claims that Depui et al never exemplify an embodiment without a separating layer.

Applicant's arguments have been fully considered but they are not persuasive. The Webster Dictionary defines *optional* as: involving an option: not compulsory. Further, option is defined as: 1) something that may be chosen 2) an item that is offered in addition to or in place of the standard. Thus, as noted by the applicant himself, the separating layer and alkaline substance are optional embodiments. The word "optional" in itself clearly denotes that if one were to exclude the *optional* separating layer and *optional* alkaline substance, it would not be detrimental to the dosage form. In regards to applicant's argument that if the separating layer and alkaline substance are excluded, then Depui et al would not be stable and enabled. Again, it is pointed out that if the separating layer and alkaline substance were absolutely critical to Depui's invention, then Depui would not insert the word optional. Additionally, column 10, lines 29-220 is pointed out wherein Depui states, "the optionally applied separating layer(s) is not essential for the invention." Lastly, page 13 of instant specification should be noted since it states that the instant dosage form can include alkaline substances, just as Depui et al state the optional use of an alkaline substance.

In regards to the argument that Depui does not exemplify the instant invention, the examiner points out that disclosed examples and preferred embodiments do not constitute a teaching away form a broader disclosure or nonpreferred embodiment. See In re Susi.

In regards to the "consisting essentially of" language, the examiner points out that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. The instant claim language does not exclude Depui's additional layers since they are not detrimental to the dosage form and as discussed above, are optional.

Applicant argues the merits of US patent 4,786,505, hereafter referred to as Lovgren et al. Appellant argues that Lovgren et al require a separating layer and alkaline substance; thus a skilled artisan would not be motivated to make a dosage form without the separating layer and alkaline substance.

Applicant's arguments have been fully considered but they are not persuasive. Firstly, the examiner relies upon Lovgren *solely* for the purpose of demonstrating the state of the art wherein a formulation containing only a single active, i.e. a proton pump inhibitor, is known in the art . The examiner does not rely on Lovgren's dosage formulation per se. Depui et al is utilized as the primary reference and discloses and suggests the broad aspect of the instant invention.

For argument sake, even if the secondary reference were removed, the examiner points out that Depui et al would still read over the prior art. Depui states in the section titled "Background of the Invention" that it is known to formulate dosage forms containing only proton pump inhibitors or prokinetic agents respectively. Therefore, the limitation of claim 35 is not a novel concept. It is acknowledged that Depui teaches the advantages of combination therapy (proton pump inhibitors and prokinetic agents);

however "a known or obvious composition does not become patentable simply because it is described as somewhat inferior" See In re Gurley. Further, the examiner points to column 2, lines 25-31 wherein the reference states that "combination therapy is considered for patients whose predominant symptom is regurgitation...those with respiratory problems...those with cough and hoarseness related to reflux disease." Therefore, it is quite clear to a skilled artisan that if a patient did not experience the above symptoms as discussed by Depui, one would utilize a single active. The combination therapy discussed by Depui is an alternative embodiment.

Applicant argues a side-by-side comparison of Depui et al and Lovgren et al. It is argued that the results demonstrate that without a separating layer, a stable dosage form is not yielded.

Applicant's arguments have been fully considered but they are not persuasive. As discussed previously, Lovgren's formulation is not relied upon to make the rejection of instant invention's formulation. Further, as discussed above, the instant invention is rejected over Depui et al alone without Lovgren et al's teachings. Therefore, the discussion of comparing Depui and Lovgren is rendered moot.

Applicant argues that the claimed invention as a whole is more stable since the enteric coating is stable because the active layer is homogenous and non-porous. Applicant argues that the instant invention utilizes a Wurster type bed coater, which distinguishes it from the prior art. It is argued applicant utilizes effective parameters to accomplish

The examiner points out that the applicant is relying on an argument of degree; i.e. the degree of stability of the instant invention compared to the prior art. However, these features are not recited or defined by the claims to distinguish it over the prior art.

In regards to the Wurster-type fluidized bed coater, firstly it is noted that only the process claims recite this limitation and not the product claims. Therefore, the distinguishable features argued by the applicant in regards to the product are moot. Further, the examiner points out that the applicant has not provided evidence only arguments demonstrating that a different and patentably distinguishable product is produced. Page 9 of instant specification is pointed out wherein applicant states that the: "Wurster'" type fluid bed or the like in which the coating process is carried out minimizes the abrasion caused by rotogranulation. From this statement, it can be ascertained that the claimed bed coater only minimizes abrasion and does not provide for any distinct features. Further, applicant argues that the Depui et al's process requires multi-step process and the instant invention does not require this; however it is pointed out that the process claims recite open claim language that does not exclude Depui's steps.

In regards to the use of "effective parameters" utilized in the instant invention, the examiner points out that it is obvious to one of ordinary skill in the art to manipulate the conditions set forth by the prior art to obtain the best possible results. Therefore, finding effective parameters is a routine process practiced by one of ordinary skill in the art. Further, applicant does not recite these effective parameters in the claims to enable one skilled in the art to product the same "superior product".

Therefore, the rejections are maintained and the claims are not distinguishable over the prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:00) with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SSG

May 25, 2004

MICHAEL G. HARTLEY
PRIMARY EXAMINER